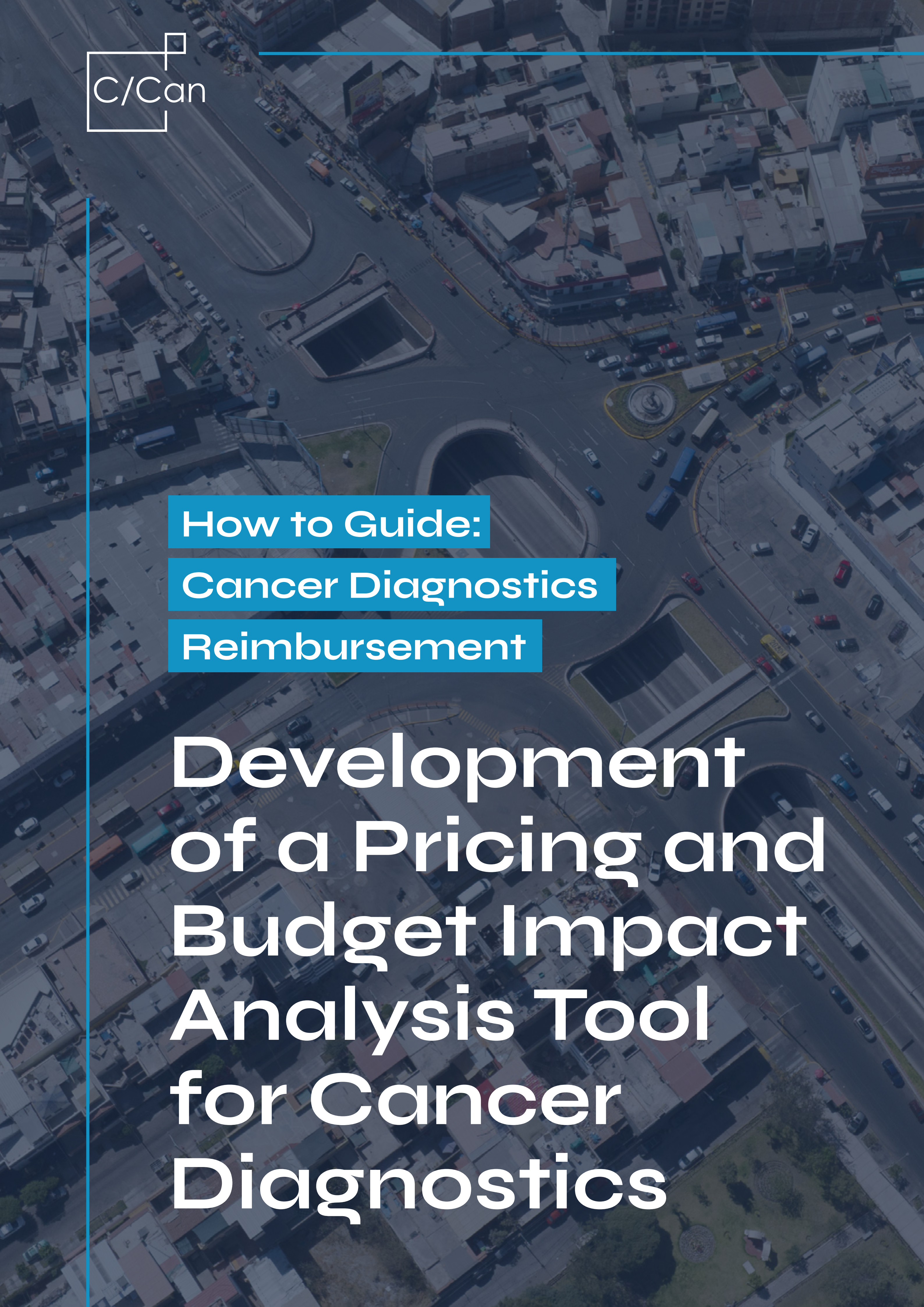

C/Can

How to Guide:
Cancer Diagnostics
Reimbursement

Development of a Pricing and Budget Impact Analysis Tool for Cancer Diagnostics

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Foreword

This document summarises the steps and procedures for developing a decision support model for financial coverage of cancer diagnostics from the perspective of the payer. The model is designed to provide decision-makers with comprehensive insights into the budget implications of expanding reimbursement for cancer diagnosis.

It outlines a methodology for estimating the budgetary consequences of including diagnostic services in a defined coverage scheme, such as a Universal Health Coverage (UHC) programme. These services are grouped into standardised packages, allowing for flexible adaptation to different health system capacities and resource levels.

The approach presented here aims to support decision-makers with evidence on pricing cancer diagnostic procedures based on national or international clinical guidelines, combined with a Budget Impact Analysis (BIA) to model the financial implications of adopting or scaling up diagnostic reimbursement. It provides a practical framework that can be used by resource allocation actors (ministries of health, national health insurance agencies, private insurance companies) to simulate the cost of diagnostic inclusion across a range of cancer types and policy options, from essential to comprehensive test packages.

This document is intended to serve as a technical guide. Any budget impact assessment for the inclusion of diagnostic services in a specific country or jurisdiction should be conducted in alignment with local cancer treatment guidelines, financing arrangements, and health system priorities. The model and methods presented here should be adapted, interpreted, and validated through a context-specific, multi-stakeholder consultation process.

1. Introduction

Budget Impact Analysis (BIA) is a financial assessment tool used to estimate the expected change in healthcare expenditure resulting from the adoption of a new health intervention. In the context of cancer diagnostics, BIA helps decision-makers understand the affordability and financial feasibility of expanding reimbursement for diagnostic tests, especially under conditions of limited resources and fixed budgets.

Unlike Cost-Effectiveness Analysis (CEA), which assesses whether an intervention provides good value for money based on health outcomes, BIA focuses on budgetary impact, providing non-discounted, annual projections over a short- to mid-term horizon, typically aligned with national budget cycles (e.g., 1 to 5 years). BIA evaluates scenarios comparing the status quo to the introduction of a new diagnostic service, considering population needs, unit costs, and levels of coverage[1].

The primary purpose of BIA is to:

- Estimate the financial consequences of including new diagnostic tests in reimbursement lists or UHC benefit packages.
- Quantify the impact on resource consumption and provide actionable forecasts for policy and budget planning.
- Inform affordability assessments, identifying scenarios where interventions, though cost-effective, may not be financially viable.
- Support evidence-based decision-making for resource allocation, reimbursement, and policy design.

This guide provides a structured methodology to develop a budget impact model for cancer diagnostics. It is designed to be flexible and adaptable to local contexts and data availability. It complements other tools such as CEA and public health impact assessments, enabling decision-makers to assess not only what works, but also what can be paid for.

[1] Yagudina RI, Kulikov AU, Serpik VG, Ugrekhelidze DT. Concept of Combining Cost-Effectiveness Analysis and Budget Impact Analysis in Health Care Decision-Making. Value Health Reg Issues. 2017 Sep;13:61-66. doi: 10.1016/j.vhri.2017.07.006. Epub 2017 Sep 12. PMID: 29073991.

2. Step-by-step Framework for Budget Impact Analysis

This guide has been developed in alignment with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) standards for Budget Impact Analysis (BIA), adhering to recognised best practices[2]. It offers a structured, step-by-step approach tailored to support informed decision-making for cancer diagnostics reimbursement, emphasising transparency, consistency, and adaptability across healthcare settings.

Each section of the guide integrates ISPOR's core recommendations, including establishing the analysis scope, capturing relevant data, creating budget models, and conducting scenario and sensitivity analyses. By following these principles, the guide equips decision-makers with a reliable framework for effective budget planning and resource allocation.

Key steps include:

- Needs assessment and stakeholder consultation
- Developing diagnostic packages
- Data collection and validation
- Developing a budget forecast model
- Scenario analysis and sensitivity testing
- Reporting and communication of results

NEEDS ASSESSMENT AND STAKEHOLDER CONSULTATION

The first step in developing the model is to identify gaps in diagnostic coverage and engage relevant stakeholders to define the model's scope and objectives. The rationale for initiating a budget impact analysis may vary, from persistently low coverage of diagnostic services in public schemes to rising demand combined with emerging fiscal space for reimbursement.

A structured needs assessment can be conducted through the following process:

1. Conduct an epidemiological assessment to understand the burden of cancer in the country, region or city. This includes reviewing data on cancer incidence, stage at diagnosis, and geographic or demographic disparities in disease patterns.
2. Review existing data on the coverage of cancer diagnostics under current financing schemes, and identify theoretical or documented gaps. This may include analysis of public expenditure reports, insurance coverage data, and out-of-pocket spending on diagnostic services.

[2] Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysisprinciples of good practice: Report of the ISPOR 2012 budget impact analysis good practice II task force. Value Health. 2014;17(1):5-14.

3. Facilitate consultations with stakeholders, including payers (such as ministries of health or national insurance agencies), medical personnel, patient representatives, and other parties, to discuss observed coverage gaps and determine the type of evidence required to inform policy responses.
4. Documentation of the actual coverage gaps and prioritising needs and interventions across evidence generation, advocacy and implementation.
5. Assess whether a modelling exercise is required to unlock additional financial coverage for diagnostics.

DEVELOPING DIAGNOSTIC PACKAGES

Once diagnostic coverage gaps have been identified and stakeholder priorities established, the next step is to define standardised diagnostic packages that reflect clinical guidelines, resource availability, and the financial scenarios identified during the needs assessment.

These packages (e.g., essential, comprehensive) are designed to align with varying levels of health system capacity and budget availability. Clinical guidelines typically specify the diagnostic tests required for each cancer, which may vary according to factors such as stage at diagnosis or disease subtype.

Where up-to-date local guidelines exist, they should be used as the foundation for package development. In contexts where local guidelines are unavailable or incomplete, internationally recognised sources, such as the National Comprehensive Cancer Network (NCCN®), the European Society for Medical Oncology (ESMO) or others, may be used, based on the preferences of the national medical community and regulatory authorities.

Aligning clinical guidelines with actual practices is essential to ensure that the model reflects local standards effectively. Engaging medical experts and relevant authorities helps verify that the guidelines used as the model´s foundation are consistent with established practices. These experts will also play a key role in defining tiered diagnostic packages, identifying which tests are essential and must be conducted for each patient, and which may be optional or deferred in cases of limited resources. This will terminate in categorisation of various cancer diagnostic packages, for example:

- Essential package: Include a list of core tests that are clinically necessary to establish a diagnosis.
- Extended package: Include all tests in the essential package plus additional investigations needed to determine precise staging or eligibility for comprehensive treatment.

PRICING DATA COLLECTION AND VALIDATION

Accurate estimation of the budget impact of diagnostic reimbursement depends on the availability of reliable cost or price data. It is essential to distinguish between **costing** and **pricing**, as the relevance of each varies and impacts data collection differently depending on the healthcare setting.

- **Costing** refers to determining the actual expenses incurred in delivering a service, including salaries, equipment, overheads, and other operational costs. Cost data is typically used in fully public systems where the government or health authority needs to understand the resources required to fund services directly.
- **Pricing**, on the other hand, is the amount charged to the payer (e.g., government, insurance, or patients) by the provider. Pricing data is relevant in settings where services are billed to a third-party payer, as in private or mixed healthcare models, and may include a margin over actual costs.

Data collection and validation should therefore be tailored to gather either cost or price data based on the context, ensuring the model reflects the financial structure in place. In fully public systems, data collection will focus on costs, while in systems with third-party payers, prices charged by providers will be more relevant. Data for diagnostic tests will be collected from facilities that will be expected to provide the services to ensure accuracy. In some cases, sampling techniques should be employed.

To make the model generalisable across different payment frameworks, users should adapt the following steps based on their local context, ensuring that the data reflects how services are financed, whether through government, private insurers, or direct patient payments. The core components include:

- Collecting Costing/Pricing Data: Gather data from a representative sample of facilities expected to perform diagnostics. Include guidance on appropriate sampling methods and strategies for addressing missing data to ensure comprehensive coverage.
- Validation Process: Outline steps for validating the collected data with input from experts in the domain. This step is critical to maintain consistency and accuracy, regardless of the funding model.
- Calculating Cost/Price Averages: When possible, use weighted averages based on facility patient volume to improve representativeness. To address variability, compute confidence intervals using appropriate statistical distributions, and apply resampling methods (e.g., bootstrapping) where needed. This ensures that estimates reflect uncertainty and enhance model reliability across healthcare settings.

The outcome of this step is a structured database containing the prices or costs of diagnostic services, which serves as a key input for building the budget impact model. This database provides the foundation for estimating expenditures, ensuring alignment with the local healthcare payment structure, and enabling informed financial planning across a range of reimbursement scenarios.

BUILDING A BUDGET FORECAST MODEL

This section guides users through building a spreadsheet-based BIA model for cancer diagnostics. The model estimates the budget required for covering diagnostic services under different coverage scenarios, using local or global data inputs. Each step corresponds to a worksheet or set of calculations in the spreadsheet.

Step 1 (forecast eligible population and cancer incidence)

The first step is to forecast population needs (eligible population and cancer incidence). Incidence rates for each cancer can be obtained from the local population-based cancer registries or estimated from global reporting tools, like the Global Cancer Observatory (GCO) database or the Global Burden of Disease (GBD) and forecasted over time. In the GCO database, the forecast is usually calculated only at 5-year intervals. As such, an interpolation method can be used to fill in the data for the interim years. For cancer types for which no forecasted data were available in the GCO database, past incidence rates can be retrieved from various databases and an extrapolation method is used to predict future incidence rates (scenarios for budget impact analysis are usually 5 years or less). The final product of this step is a table of cancer incidence (new cancer cases) over time.

How to do it:

- Create a new sheet titled “Incidence Forecast”.
- In column A, list the cancer types (e.g., Breast, Cervix, Colorectal).
- In columns B onward, enter the years of analysis (e.g., 2025 to 2030).
- Populate the table with the number of new cancer cases per year and cancer type.
- Use data from local cancer registries if available.
- If not available, extract incidence forecasts from the GCO or GBD.
- If needed, apply:
  - Interpolation between 5-year GCO projections.
  - Extrapolation from past trends where no forecasts exist.
- Columns for case mix may be added (e.g., % by stage or age) to reflect diagnostic complexity (optional)

Step 2 (Define coverage levels)

The next step is to establish the degree of coverage for each of the three dimensions of Universal Health Coverage (UHC) to be included in the budget impact analysis for each cancer type, based on clinical guidelines or expert consensus (this defines the policy scenario under which the budget will be calculated): the proportion of the population covered, expressed by the share of cancer patients eligible for diagnostic services; the range of services covered, expressed by the percentage of patients receiving each type of diagnostic package (in our case we have defined 2 packages); and cost coverage, expressed by the level of out-of-pocket co-payment required from patients. If multiple coverage schemes are considered together in the BIA (for example, public insurance, private insurance, out-of-pocket payments, etc.), either multiple sheets could be created (one for each coverage scheme), or a weighted average can be calculated.

How to do it:

- Create a sheet titled “Coverage Parameters”.
- In column A, list cancer types.
- In column B, list the coverage parameters for each tumour type:
  - Proportion (%) of patients covered by the scheme (Population Coverage).
  - Proportion (%) receiving Essential Package (Service Coverage).
  - Proportion (%) receiving Comprehensive Package (Service Coverage).
  - Proportion (%) of costs covered by the payer (Cost Coverage).
- In columns C onward, enter the years of analysis (e.g., 2025 to 2030).

This worksheet is prepared to ramp up coverage over the time period considered for the analysis. The values for coverage will be used as an annually estimate in step 6.

Step 3 (Define packages)

The next step is to combine the various diagnostic tests into diagnostic packages for each tumour type based on the guidelines adopted for diagnostic workup (see "Developing diagnostic packages"). This worksheet serves as the master input for package composition.

How to do it:

- Create a sheet titled "Diagnostic packages".
- Set up the following columns:
  - › Column A: Cancer Type (e.g., Breast, Cervix, Colorectal).
  - › Column B: Diagnostic Test Name (e.g., Core biopsy, Chest CT, Pelvic MRI).
  - › Proportion (%) receiving Comprehensive Package (Service Coverage).
  - › Column C onward: Diagnostic package (Essential, Comprehensive).
    - Fill these cells with Y/N depending if the diagnostic test is included in each of the packages according to the guideline adopted or developed.

Multiple packages can be defined according to the guidelines or expert advice used. In this case, we limit the analysis to two packages: essential and comprehensive.

Step 4 (Integrate and summarise test-level raw data)

The next step is to input raw price data collected before (see "Pricing data collection and validation") for each diagnostic test and calculate a representative unit price for each test (e.g., average, median, or resampled estimate) to be used in package costing. Pricing data should be in local currency or converted using current exchange rates for comparison. Document the data source for each price (e.g., public tariff list, invoice, reimbursement claim) if available.

How to do it:

- Create a sheet titled "Raw Test Prices".
- Set up the following columns:
  - Column A: Cancer Type (e.g., Breast, Cervix, Colorectal).
  - Column B: Diagnostic Test Name (e.g., Core biopsy, Chest CT, Pelvic MRI).
  - Column C onward: One column per facility or provider.
    - Fill these cells with the price charged to the payer by each facility for the test.
    - If a facility doesn't offer a specific test, leave the cell blank or mark as "N/A".
  - Add a Summary Column (e.g., Column G) to calculate the representative unit price of each test.
- To calculate the representative unit price:
  - If the number of facilities is sufficient and price variation is small, calculate the simple average.
  - If the price distribution is skewed or the number of observations is low, apply resampling methods (e.g., bootstrapping) to estimate the mean with confidence intervals.

This worksheet serves as the master pricing input for the model. Pricing data will feed into the next step to calculate the cost of each package per tumour type.

Step 5 (Assign costs to diagnostic packages)

The objective of this step is to compute the total cost of each diagnostic package (e.g., Essential or Comprehensive) for each cancer type by summing the unit prices of the individual tests that comprise the package.

How to do it:

- Create a sheet titled "Package Unit Costs".
- Set up the following columns:
  - Column A: Cancer Type (e.g., Breast, Cervix, Colorectal).
  - Columns B and C: Total Package Cost (in our case for "Essential" and "Comprehensive" packages). This will be calculated by summing the test-level unit prices for all tests that belong to the specified cancer type and package.
  - Additional columns for each additional package to be included.
  - Add a Summary Column (e.g., Column G) to calculate the representative unit price of each test.
- To calculate the total package cost:
  - Use the representative test prices from the "Raw Test Prices" sheet (from Step 4).
  - For each cancer type and package, sum the unit prices of those tests.

This worksheet calculates the unit cost per patient for each diagnostic package. These values will now feed into the budget forecast model, where the package cost is multiplied by the forecasted number of patients and coverage parameters.

Step 6 (Build the annual forecast per cancer type)

The budget forecast model can then be prepared to determine the budget required for cancer diagnostics by estimating the annual cost of reimbursing diagnostic services for each cancer type by combining incidence forecasts, coverage levels, and package unit costs. The time horizon for BIA needs to be adapted to the needs of the budget holder and should align with the budgeting process of the health system of interest. Typically, BIA results are presented annually for a period of 3-5 years though extended projections (e.g., up to 10 years) may be included.

How to do it:

- Create a sheet titled “Cancer Budget Forecast”.
- Set up the following columns:
  - Column A: Cancer Type (e.g., Breast, Cervix, Colorectal).
  - In columns B onward, enter the years of analysis (e.g., 2025 to 2030).
  - Add a summary column to calculate the annual budget per tumour type.
- The total annual budget per tumour type is calculated as follows: Total Budget year = Incidence * [(%Essential) * CostEssential + (%Comprehensive) * CostFull] * PayerCostCoverage:
  - Incidence: Incidence per tumour type and year (from “Incidence Forecast”).
  - %Essential: Proportion (%) of the cancer patients receiving Essential Package (from the “Coverage Parameters” sheet).
  - %Comprehensive: Proportion (%) of the cancer patients receiving Comprehensive Package (from the “Coverage Parameters” sheet).
  - CostFull: Cost of Full Package (from the “Package Unit Costs” sheet).
  - PayerCostCoverage: Proportion (%) of the cost of the package covered by payer (from the “Coverage Parameters” sheet)
- The total annual budget per all tumour types combined is calculated in a summary row, aggregating all annual budgets per tumour type.

The “Coverage parameters” sheet allows users to simulate different implementation strategies by adjusting variables such as the phased expansion of population coverage, allocation of diagnostic packages, and the share of costs covered by the payer. While inflation adjustments can be applied if needed to reflect long-term (> 5y) financial accuracy, it is generally not included in standard BIA models.

The model includes the total budget for each year as well as the budget per cancer type.

Step 7 (Create charts to communicate results)

The objective of this step is to generate clear and compelling graphs to support interpretation, decision-making, and presentation of budget impact results. Here is a list of suggested graphs:

Graph 1: Total Budget Over Time

- Type: Line Chart
- Purpose: Show the projected annual cost of reimbursing cancer diagnostics across all cancer types.

Graph 2: Budget Breakdown by Cancer Type

- Type: Stacked Column Chart
- Purpose: Visualise the relative contribution of each cancer type to the total annual budget.

Graph 3: Scenario Comparison

- Type: Clustered Column Chart
- Purpose: Compare different policy scenarios (e.g., base case vs. full coverage or inflation-adjusted vs. unadjusted).

Graph 4: Cost per Patient vs. Coverage Level

- Type: Scatter Plot or Bubble Chart
- Purpose: Illustrate trade-offs between expanding coverage and average cost per covered patient.

Graph 5: Diagnostic Cost Drivers (Per Cancer Type)

- Type: Horizontal Bar Chart
- Purpose: Show which diagnostic tests contribute most to the cost of each package, helping identify major cost drivers.

This spreadsheet model enables policy and technical teams to estimate the financial requirements of cancer diagnostic reimbursement under varying coverage and cost scenarios. It supports evidence-informed decision-making by translating epidemiological and pricing data into actionable budget forecasts.

SCENARIO ANALYSIS AND SENSITIVITY TESTING

Sensitivity and scenario analysis are essential components of a robust Budget Impact Analysis, allowing users to test the stability of model results under varying assumptions and to explore the financial implications of different policy decisions.

Scenario analysis

Scenario analysis involves changing structural assumptions in the model such as the choice of diagnostic package (essential vs. comprehensive), the coverage rate of the population, or co-financing arrangements to evaluate the budgetary impact of alternative policy choices.

> For example, in a lower-middle-income country, the Ministry of Health plans to expand public reimbursement for cancer diagnostics beyond breast cancer to include cervical and colorectal cancers. Given fiscal constraints, the rollout will follow a phased geographic approach over five years, —starting with urban tertiary centres (covering 40% of cases), then regional hospitals (an additional 35%), and finally achieving nationwide coverage.
>
> The scenario models two policy options: A base case where only the essential diagnostic package is reimbursed throughout, and an enhanced scenario where the comprehensive package is introduced from year four.
>
> Government cost coverage is set at 80%, with a 5% annual inflation rate applied to unit costs. Incidence estimates are drawn from local registries, and prices from a mix of public tariffs and facility invoices.
>
> This scenario analysis allows policymakers to compare affordability under different rollout strategies, assess annual budget needs, and identify when donor co-financing might be needed to sustain equitable access.

Sensitivity analysis

Sensitivity analysis complements scenario analysis by testing the robustness of the model's results to uncertainty in key input parameters. It involves systematically varying these parameters within plausible ranges to assess how much they influence the overall budget estimates. This includes:

- **One-way sensitivity analysis**, where individual parameters (e.g., unit costs, incidence rates) are varied one at a time to identify critical cost drivers.
- **Multi-way sensitivity analysis**, which simultaneously adjusts multiple variables to assess interaction effects.
- **Probabilistic sensitivity analysis (PSA)**, where probability distributions are assigned to uncertain parameters and simulations (e.g., Monte Carlo methods) are used to quantify the range and probability of budget outcomes.

Typical variables subject to sensitivity testing include incidence rates by cancer type, diagnostic unit costs and pricing indices (e.g., mean, median, percentiles), inflation assumptions, and the parameters related to coverage, —both in terms of population and services, as well as cost-sharing arrangements between payers and patients.

Where data availability allows, visual tools such as tornado diagrams, spider plots, or budget distribution histograms can be used to clearly communicate which parameters drive budget variability and where uncertainty may have significant policy implications. Sensitivity analysis plays a critical role in enhancing transparency and supporting financial risk management by identifying the conditions under which the proposed intervention remains affordable, thereby improving the confidence and credibility of the budget impact estimates.

For example, in an LMIC preparing to introduce public reimbursement for breast and cervical cancer diagnostics, policymakers face significant price variability across regions and providers. Diagnostic services are delivered through a mix of public hospitals, private laboratories, and NGO-supported centres, with limited regulation of tariffs. Given these inconsistencies, the Ministry of Health seeks to understand how variations in unit prices could affect the projected budget.

A sensitivity analysis is conducted to explore the impact of pricing uncertainty on total annual expenditures. The base model uses the average unit price across sampled providers. The analysis then varies these prices by ±25%, reflecting potential procurement efficiencies or inflation-driven increases. Additional sensitivity tests examine changes in cost-sharing arrangements, from 100% public coverage to scenarios with 20% patient co-payments.

Results are presented using tornado diagrams to identify the diagnostic tests with the greatest budgetary influence and to visualise the range of potential fiscal outcomes. The findings help the Ministry prioritise which inputs require stricter price controls or centralised purchasing strategies and guide contingency planning in the event of inflation or service expansion.

Variable Customization

The model is designed to support flexible adjustment of key parameters, enabling tailored scenario and sensitivity analyses across diverse implementation settings.

Forecasted cancer incidence can be modified to reflect changes in disease burden over time. This includes adjustments for increased detection resulting from expanded screening programs, demographic shifts, or improved reporting systems. These projections form the foundation for estimating the number of patients eligible for diagnostic reimbursement.

The composition of diagnostic packages can also be adapted, allowing users to select between essential and comprehensive configurations, or to define hybrid packages based on national clinical guidelines and available resources. This flexibility ensures alignment with both clinical relevance and fiscal feasibility.

Population coverage is another adjustable parameter. The model permits the specification of the proportion of cancer patients eligible for reimbursement, as well as the percentage receiving each diagnostic package type. This allows for phased roll-out strategies or selective targeting of high-priority groups, accommodating real-world constraints in uptake or service availability.

Unit pricing can be calibrated using different cost indices derived from collected data, such as mean, median, or specific percentiles. Annual inflation adjustments can be incorporated to model year-over-year price changes, enabling more accurate long-term projections. The model accommodates variability across providers and facilities, which is particularly important in settings with mixed public-private service delivery.

Cost-sharing arrangements between the public payer and patients are also customizable. Users can define the proportion of diagnostic costs covered by the health system versus those paid out-of-pocket by patients, allowing the model to reflect diverse financing strategies including co-payment mechanisms or targeted subsidies.

In addition, all parameters can be customised over time for the full duration of the analysis period, allowing the model to reflect phased implementation strategies or planned policy changes. For example, coverage may increase gradually from tertiary centres to nationwide scope, cost-sharing levels may decrease as fiscal space expands, or comprehensive packages may be introduced after an initial period of essential-only coverage.

By enabling dynamic adjustment of these variables, the model supports robust policy exploration and fiscal planning under uncertainty.

REPORTING AND COMMUNICATION OF RESULTS

The final outputs of the budget impact analysis process include:

- A structured model to estimate the cost of standard cancer diagnostic procedures, developed in line with national (or international) clinical guidelines.
- A set of budget forecasts modelling the financial implications of introducing or scaling up reimbursement for diagnostic services under various policy and implementation scenarios.
- Aggregated budget estimates across all included cancer types, providing a comprehensive view of projected expenditure.
- Evidence-based recommendations for the payer or budget holder (typically the Ministry of Health, a national health insurance agency, or other designated authority) highlighting priority areas for diagnostic reimbursement based on financial feasibility.

To maximise the practical use of these outputs, users are encouraged to present the results in formats that support informed decision-making and intersectoral dialogue. This may include preparing a concise policy brief that summarises budget implications, coverage scenarios, and policy recommendations. Graphical outputs such as budget trend lines, breakdowns by cancer type, or scenario comparisons can enhance understanding for non-technical stakeholders.

Because the tool is designed from the payer perspective, outputs should be framed around the concerns of those responsible for allocating public funds, such as fiscal risk, sustainability, and alignment with coverage mandates.

Results may also inform internal planning processes, be annexed to strategic purchasing proposals, or support applications for external funding. Communication should be tailored to the needs of each audience, ensuring clarity while preserving the rigour of the analysis.

VALIDATION OF THE MODEL

The validation of this budget impact model was conducted in line with the recommendations included in the ISPOR Task Force on Budget Impact Analysis (2). The validation process included the following elements:

- Face validity was ensured through the use of nationally and internationally recognised cancer treatment guidelines to define diagnostic packages. These packages were reviewed by local oncology specialists to confirm clinical appropriateness and alignment with standard practice.
- **Stakeholder validation** was achieved through the review and application of the model by the **Ministry of Health of Georgia** and local partners. The model was used to estimate the budgetary implications of expanding diagnostic reimbursement within the country's Universal Health Coverage (UHC) program, providing real-world policy relevance and contextual input.
- An expert review was conducted by an independent health economist with expertise in cancer care financing, who assessed the methodological robustness of the model, including its structure, assumptions, and sensitivity analysis framework.

While formal external validation using historical expenditure data was not feasible due to limited availability of longitudinal reimbursement datasets, internal validation steps were conducted to ensure consistency and correctness in calculations and data linkages across the model.

This multi-tiered validation approach ensures the model is technically sound, contextually grounded, and appropriate for informing reimbursement decisions in low- and middle-income countries.

LIMITATIONS OF THE MODEL AND FURTHER AREAS OF DEVELOPMENT

While the model provides a practical framework for estimating the budgetary impact of cancer diagnostic reimbursement, several limitations should be noted in line with international good practice for budget impact modelling:

- Limited flexibility for partial or repeat diagnostics: The current model is not dynamic enough to simulate cases where not all tests in a diagnostic package are performed, or where repeat testing is required (e.g., follow-up CT after inconclusive imaging). Such clinical variability is common in real-world diagnostic pathways and may affect actual costs.
- Lack of hybrid package modelling: At present, the model supports binary package selection (either essential or comprehensive). It does not allow for scenarios in which a patient receives a subset of tests from both tiers. Incorporating a modular or test-level cost structure would improve realism and policy relevance, though it would also increase the complexity of model use and data input requirements.
- Exclusion of diagnostic tests for treatment monitoring: The scope of the model is limited to diagnostics at the point of cancer detection. It does not currently account for imaging or laboratory tests used for monitoring treatment response or disease progression, which may constitute a significant share of diagnostic expenditure in practice.
- Simplified pricing approach: The model uses average unit prices for cost estimation. While sufficient for high-level planning, this may not capture provider-level variation. A weighted average approach (adjusting for facility test volumes or regional pricing differences) could improve accuracy, provided such data is available.
- No adjustment for case-mix complexity: The model assumes uniform cost per case, without accounting for variation due to tumour stage, comorbidities, or diagnostic intensity. While this simplifies calculations, it may underestimate costs in tertiary centres or referral hospitals managing more complex cases. This limitation could be partially addressed by incorporating variability measures derived from cancer registry data, assuming an increase in the complexity of the model.

Addressing these limitations in future iterations could enhance the model's utility for more granular planning, strengthen equity considerations across facility types and population groups, and support more advanced financing scenarios such as bundled payments or performance-based reimbursement.

3. Acknowledgements

We thank all C/Can partners, and in particular the Embassy of Switzerland in Georgia, as the main funder of the tool's development. We also extend our gratitude to Boehringer Ingelheim and Roche for supporting the dissemination of the tool through this How-To Guide.

4. Annex: use cases

The Budget Impact Analysis (BIA) tool presented in this guide is designed to support payers in evaluating the financial implications of introducing or modifying cancer diagnostic services. It can be applied across a range of policy and planning scenarios, from assessing the affordability of new service packages to exploring population coverage expansions or comparing alternative configurations of care.

While designed to be accessible and easy to use, the tool also allows for more complex scenarios to be modeled, depending on data availability and policy needs. The tool can be applied across different types of insurance schemes, including national health insurance, social security systems, or targeted public programs, and is flexible enough to accommodate varying degrees of service coverage, provider arrangements, and population targeting.

In addition to the examples showed before, this section presents illustrative use cases that demonstrate the versatility of the tool. Each example highlights a distinct policy question faced by payers, showing how the BIA can inform strategic decisions by quantifying expected budgetary consequences over time.

Use case 1: Introducing Public Financing for Cancer Diagnostics in a Privately Dominated System

In a country where cancer diagnostic services have been provided solely by private providers and financed out-of-pocket by patients during the past 20 years, the national health financing agency is considering the introduction of public coverage for a core set of diagnostics. The aim is to reduce financial barriers to access and align with broader health system reform goals. Until now, there has been no dedicated public budget or reimbursement scheme for diagnostics, posing challenges for equitable access and early detection.

To inform the funding decision, a Budget Impact Analysis is conducted from the payer perspective. The analysis projects the additional budgetary outlay required if the public payer were to reimburse a set of diagnostic packages for high-priority cancers such as breast and lung. Market-based test pricing, target population estimates, and phased coverage assumptions are used to model the annual and cumulative fiscal impact over five years.

This application enables the payer to evaluate affordability under different rollout scenarios, anticipate funding needs, and explore potential contracting mechanisms with private providers. The BIA supports sound fiscal planning while contributing to a more equitable diagnostic landscape.

Use case 2: Comparing Basic and Enhanced Cancer Diagnostic Packages

As part of a national policy to standardize cancer diagnostic services under the public insurance scheme, the payer must choose between two diagnostic packages. The basic package covers essential tests required to confirm a diagnosis, while the enhanced package adds advanced tools such as staging scans or molecular profiling that may improve clinical outcomes but come at a higher cost.

A Budget Impact Analysis is applied from the payer's perspective to compare the incremental cost of covering each package under the insurance scheme. The tool estimates the eligible population, unit costs, and projected uptake of services. It models the fiscal consequences over a multi-year horizon, providing insight into how each option would affect the payer's budget envelope.

The analysis enables the payer to assess trade-offs between expanded diagnostic precision and financial sustainability. It also facilitates structured discussion on potential sequencing strategies, allowing the enhanced package to be introduced gradually or targeted to subpopulations with the highest clinical need.

Use case 3: Expanding Diagnostic Coverage to an Uninsured Population Group

Currently, cancer diagnostic services are reimbursed only for individuals enrolled in the national insurance scheme, primarily formal sector employees. A large portion of the population remains uninsured and must pay for diagnostic care out-of-pocket. The national payer is considering expanding its coverage to include this underserved group, as part of an effort to advance universal health coverage.

Using a Budget Impact Analysis tool tailored to the payer perspective, the analysis estimates the additional financial commitment required to fund diagnostic services for the previously excluded population. It compares the current budget allocation with the projected outlays under a universal coverage scenario, incorporating assumptions about uptake, incidence, and test pricing.

The results equip the payer with actionable evidence on the cost of expanding entitlements, helping to assess affordability, identify fiscal risks, and guide phased inclusion strategies. The BIA also highlights potential funding gaps or areas where co-financing or donor support may be needed to maintain equity without compromising financial sustainability.

5. Contact

For more details on the budget impact analysis tool, please contact:

CONTACT INFORMATION

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